REMARKS

The present communication responds to the non-final Office action of August 3, 2006 in which the Examiner rejected claims 1-12. Claim 1 was rejected due to insufficient antecedent basis, claims 1-12 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 5,304,152 ("Sams"), and claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as unpatentable over Sams as applied to claim 1 and further in view of U.S. Patent 6,146,361 ("DiBiasi").

The claim rejections are traversed for at least the reasons articulated below, and reconsideration is requested.

Claims 30-81 are now pending in the application. Applicant has cancelled original claims 1-29 and claims numbered 1-12 from the preliminary amendment filed on September 13, 2005 without prejudice. New claims 30-81 have been added to clarify the claim form, claim numbering, and which claims are pending in the application. New claims 30-47 correspond to originally filed claims 1-18. New claims 30-81 do not add new matter.

Amendments to the Specification

In the specification, paragraph [0001] has been amended to reflect the correct filing date and application number of German Application No. 101 63 328.9 filed on December 21, 2001. A Supplemental Request for Corrected Filing Receipt was filed with the Office on August 14, 2006.

Additionally, paragraph [0054] has been amended to correct the reference numeral.

Rejection under 35 U.S.C. § 112

Claim 1, rejected due to insufficient antecedent basis, has been cancelled, thereby obviating this rejection.

Rejection under 35 U.S.C. § 102

Claims 1-10 were rejected under 35 U.S.C. § 102(b) as anticipated by Sams.

Claims 1-10 have been cancelled and new claims 30-43, 48-59, and 64-77 will be discussed with regard to the 35 U.S.C. § 102(b) rejection.

For an invention to be anticipated under 35 U.S.C. § 102(b), a reference must disclose each and every element of the claimed invention. New claim 30 is directed to an administering apparatus for administering a fluid product in doses, the administering apparatus including a casing including a reservoir for the product, a driven device for performing a delivery stroke in an advancing direction along a translational axis, to deliver a product dosage, a drive device for performing a delivery movement to deliver the product dosage, a dosage setting member coupled to the driven device such that a rotational dosing movement performed by the dosage setting member and the driven device about the translational axis, causes an axial translational dosing movement of the dosage setting member relative to the driven device and the casing, a translational stopper positioned opposite and axially facing the dosage setting member, in an axial end position of the dosage setting member, and a rotational block which, in the end position of the dosage setting member, permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction.

Sams discloses a dispensing device having a shell (11) which may be connected to a container (14) for a fluid to be dispensed, such as an injectable pharmaceutical compound. The device has a fixed first threaded member (21) and a second threaded member (22) surrounding the first member, the first and second members each having equi-spaced threaded segments (27 and 29) with non-threaded segments (28) therebetween whereby the second member will be wound axially when rotated about the first member but may be positioned for axial sliding movement with respect to the first member. A plunger (23) is slidably mounted within the first member (21) and has a portion (33) engageable with the threads of the second member. A dose setting sleeve (53) surrounds the second member and has threads (54) engaged with the device shell, the sleeve being coupled to the second member for rotation therewith. A dose is set by winding the second member (22) away from a fixed stop (25) until the sleeve (53) indicates the required dose amount, whereafter the second member (22) is slid axially back to the fixed stop (25), the plunger (23) being thrust forwardly thereby to expel fluid from the container.

Sams does not disclose a rotational block which, in the end position of the dosage setting member, permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction.

To the contrary, Sams discloses that,

> [f]or the purpose of dispensing a measured dose the device is set to dose zero by winding end piece 59 clockwise until indicator 53 is wound forward sufficiently to indicate "0" through window 57. In that configuration, blocks 64 engage with recesses 69 of face 70 and button 68 abuts or is closely adjacent end piece 59. If a dose had fully been dispensed beforehand, member 22 rests on ring 25, whilst sleeve 53 still shows the set dose. The sleeve is wound clockwise by turning end piece 59, which drives the sleeve through splines 51 and 52, advancing the sleeve towards the front. As the blocks 64 protrude by a lesser dimension than the axial motion of member 22 when turned through 90°, re-engagement of the blocks 64 in recesses 69 takes place during the last 90°. of movement of sleeve 53 to show "0" through window 57, so re-establishing a connection between member 22 and sleeve 53. If the dose had not fully been dispensed, turning the end piece 59 will pick up member 22, and thread it forward before the sleeve 53 is reset to "0" by the action of the blocks 64 engaging in recesses 69. When the member 22 bears on ring 25 and the blocks 64 are engaged in recesses 69, end piece 59 can be turned anti-clockwise to set a new dose to be dispensed.

(Sams, col. 7, line 48 to col. 8, line 3.) Sams end piece 59 can be turned anti-clockwise when the member 22 bears on ring 25 instead of blocking the rotational dosing movement in the other, second rotational direction as in claim 30.

Furthermore, Sams discloses that,

> FIGS. 5A and 5B show a stop arrangement for the second member 22, to prevent that member being turned to selected a greater dose than remains for dispensing within the container. The member 22 has four pawls 76 arranged on its front end and which bear on the outer surface of the first member 21 or on the upper surface of the plunger 23, as the member 22 is rotated. The plunger has a recess 75 on its upper surface adjacent its threaded segment 33, into which recess one of the pawls 76 will drop to restrain further rotation of the member 22 in a dose-setting sense when the plunger has been advanced by a pre-determined distance into a container. The splines 61 connecting the end piece 59 to member 22 may be arranged to slip in the event that a pawl 76 locks member 22; once this occurs, member 22 has to be wound back through 45° to release the lock, so that the plunger 23 can be pushed back without also pushing back member 22. Should however member 22 be pushed back as well on replacing cartridge 17, the user

> need merely wind the member 22 until "0" is showing once more through window 57, to reset the mechanism. It will be appreciated that at the point at which the lock occurs the dose indicator sleeve 53 will show the number of doses remaining in the cartridge.

(Sams, col. 8, line 52 to col. 9, line 7.) Sams utilizes a slippage arrangement where member 22 has to be wound back, instead of a rotational block which, in the end position of the dosage setting member, permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction as in claim 30.

Claim 48 is directed to an administering apparatus for administering a fluid product dosage, the administering apparatus including a casing, a driven device for performing a delivery stroke in an advancing direction along a translational axis, to deliver a product dosage, a drive device for performing a delivery movement to deliver the product dosage, a dosage setting member coupled to the driven device such that a rotational dosing movement performed by the dosage setting member and the driven device about the translational axis, causes an axial translational dosing movement of the dosage setting member relative to the driven device and the casing, a translational stopper positioned opposite and axially facing the dosage setting member, in an axial end position of the dosage setting member; and a rotational block which permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction, wherein the rotational block prevents the dosage setting member from pressing axially against the translational stopper by the rotational dosing movement, wherein the rotational block includes at least one first rotationally acting stopper and at least one second rotationally acting stopper, the first rotationally acting stopper and the second rotationally acting stopper abutting against one another in the end position of the dosage setting member.

Sams end piece 59 can be turned anti-clockwise when the member 22 bears on ring 25 instead of blocking the rotational dosing movement in the other, second rotational direction as in claim 48. Additionally, Sams utilizes a slippage arrangement where member 22 has to be wound back, instead of a rotational block which prevents the dosage setting member from pressing axially against the translational stopper by the rotational dosing movement as in claim 48.

Claim 58 is directed to an administering apparatus for administering a fluid product dosage, the administering apparatus including a casing, a driven device for performing a delivery stroke in an advancing direction along a translational axis, to deliver a product dosage, a drive device for performing a delivery movement to deliver the product dosage, a dosage setting member coupled to the driven device such that a rotational dosing movement performed by the dosage setting member and the driven device about the translational axis, causes an axial translational dosing movement of the dosage setting member relative to the driven device and the casing, a translational stopper positioned opposite and axially facing the dosage setting member, in an axial end position of the dosage setting member, and a rotational block including a plurality of first rotationally acting stoppers and a plurality of second rotationally acting stoppers, abutting against one another in the axial end position of the dosage setting member, which permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction, each of the plurality of first rotationally acting stoppers forming a pair of stoppers with each one of the plurality of second rotationally acting stoppers, wherein each pair of stoppers thus formed is arranged adjacently, spaced from one another in the circumferential direction.

Again, Sams end piece 59 can be turned anti-clockwise when the member 22 bears on ring 25 instead of blocking the rotational dosing movement in the other, second rotational direction as in claim 58. Additionally, Sams utilizes a slippage arrangement where member 22 has to be wound back, instead of a rotational block comprising a plurality of first rotationally acting stoppers and a plurality of second rotationally acting stoppers, each of the plurality of first rotationally acting stoppers forming a pair of stoppers with each one of the plurality of second rotationally acting stoppers, wherein each pair of stoppers thus formed is arranged adjacently, spaced from one another in the circumferential direction as in claim 58.

Claim 64 is directed to an administering apparatus for administering a fluid product dosage, the administering apparatus including a casing, a driven device for performing a delivery stroke in an advancing direction along a translational axis, to deliver a product dosage, a drive device for performing a delivery movement to deliver the product dosage, a dosage setting member coupled to the driven device such that a rotational dosing movement performed by the dosage setting member and the driven device about the translational axis, causes an axial

translational dosing movement of the dosage setting member relative to the driven device and the casing, a translational stopper positioned opposite and axially facing the dosage setting member, in an axial end position of the dosage setting member, and a rotational block including a plurality of axially oriented, rotationally acting, stoppers which, in the end position of the dosage setting member, permit the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction.

Once again, Sams end piece 59 can be turned anti-clockwise when the member 22 bears on ring 25 instead of blocking the rotational dosing movement in the other, second rotational direction as in claim 64. Additionally, Sams utilizes a slippage arrangement where member 22 has to be wound back, instead of a rotational block including a plurality of axially oriented, rotationally acting, stoppers which, in the end position of the dosage setting member, permit the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction as in claim 64.

For at least the preceding reasons, a rejection of claims 30, 48, 58 and 64 under 35 U.S.C. § 102(b) is unwarranted.

Rejections of the Dependent Claims

Because claims 31-43, 49-57, 59 and 65-77 depend directly or indirectly from the independent claims 30, 48, 58 and 64 and incorporate all the limitations of the corresponding independent claims, they are allowable for the same reasons and, further, in view of their additional recitations.

Rejection under 35 U.S.C. § 103

Claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as unpatentable over Sams as applied to claim 1 and further in view of DiBiasi.

Claims 11-12 have been cancelled and new claims 44-47, 60-63 and 78-81 will be discussed with regard to the 35 U.S.C. § 103(a) rejection.

New claims 44-47 depend directly or indirectly from new claim 30, new claims 60-63 depend directly or indirectly from new claim 58 and new claims 78-81 depend directly or indirectly form new claim 64, and incorporate all the limitations of the independent claims. Applicant's new claims 30, 58 and 64 are discussed above. Claims 44, 60 and 78 are further directed to a cannula of at most 30 gauge forming an injection or infusion cannula of the administering apparatus. Claims 45, 61 and 79 are further directed to a cannula exhibiting a combination of outer and inner diameter not specified in ISO 9626, having an outer diameter of 320 μm at most and as thin a wall thickness as possible forming an injection or infusion cannula of the administering apparatus. Claim 46, 62 and 80 are further directed to a 31 gauge cannula. Claims 47, 63 and 81 are further directed to a 32 gauge cannula.

As an initial matter, Applicant questions the propriety of this rejection. Nothing in Sams directs the skilled artisan, or provides the requisite motivation for the skilled artisan, to select a rotational block which, in the end position of the dosage setting member, permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction as in claim 30. Nor does Sams direct the skilled artisan or provide the requisite motivation for the skilled artisan, to select a rotational block including a plurality of first rotationally acting stoppers and a plurality of second rotationally acting stoppers, abutting against one another in the axial end position of the dosage setting member, which permit the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction, each of the plurality of first rotationally acting stoppers forming a pair of stoppers with each one of the plurality of second rotationally acting stoppers, wherein each pair of stoppers thus formed is arranged adjacently, spaced from one another in the circumferential direction as in claim 58. Furthermore, Sams does not direct the skilled artisan to select a rotational block including a plurality of axially oriented, rotationally acting stoppers which, in the end position of the dosage setting member, permit the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction as in claim 64.

DiBiasi fails to remedy the deficiencies of Sams, the disclosure of which is discussed above. DiBiasi discloses a medication delivery pen for delivering medication to a patient during an injection procedure including a needle assembly having a 31 gauge needle cannula; a

cartridge assembly containing medication having a proximal and distal end, said proximal end including an array of threads and a stopper and said distal end including means for attaching said needle assembly so that medication can flow through said 31 gauge needle cannula during an injection procedure; and a dosing apparatus having opposed proximal and distal ends with an array of threads at said distal end for threaded engagement with said threads at said proximal end of said cartridge assembly, said dosing apparatus further comprising a plunger rod projecting beyond said distal end of said dosing apparatus for selective engagement with said stopper in said cartridge assembly, and means for moving said plunger rod distally in said dosing apparatus selected amounts, whereby said plunger rod moves said stopper in said cartridge assembly to dispense medication from said cartridge assembly through said 31 gauge needle cannula.

DiBiasi does not suggest a modification to include a rotational block which, in the end position of the dosage setting member, permits the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction as in claim 30 nor does DiBiasi suggest a modification to include a rotational block including a plurality of first rotationally acting stoppers and a plurality of second rotationally acting stoppers, abutting against one another in the axial end position of the dosage setting member, which permit the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction, each of the plurality of first rotationally acting stoppers forming a pair of stoppers with each one of the plurality of second rotationally acting stoppers, wherein each pair of stoppers thus formed is arranged adjacently, spaced from one another in the circumferential direction as in claim 58. Furthermore, DiBiasi does not suggest a modification to include a rotational block including a plurality of axially oriented, rotationally acting stoppers which, in the end position of the dosage setting member, permit the rotational dosing movement in a first rotational direction and blocks the rotational dosing movement in a second rotational direction as in claim 64.

Moreover, the secondary reference of DiBiasi does not cure the deficiencies of Sams. Even if they could be properly combined, the asserted combination of Sams with DiBiasi would not lead the skilled artisan to make the administrating apparatus of claims 44-47, 60-63 and 78-81.

Applicant requests, therefore, that the rejection of claims under § 103(a) over Sams in view of DiBiasi be withdrawn.

Conclusion

This paper generates a fee for additional claims and a petition fee for a one (1) month extension of time to December 3, 2006. A check is enclosed to cover the fees. The Commissioner is also hereby authorized to charge any deficiencies and credit any overpayments associated with this paper or the petition to Deposit Account No. 04-1420.

This application now stands in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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